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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,377	09/15/2003	Yanbin Liang	17565 (AP)	2517
51957	7590	02/08/2006		
ALLERGAN, INC., LEGAL DEPARTMENT 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599				
			EXAMINER CHOWDHURY, IQBAL HOSSAIN	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/663,377	<b>Applicant(s)</b> LIANG ET AL.	
	<b>Examiner</b> Iqbal Chowdhury, Ph.D.	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 7, and 56-60, drawn to isolated polynucleotide encoding COX-1 variant polypeptide, classified in class 536, subclass 23.2.
- II. Claims 1-4, drawn to an isolated polypeptide COX-1 variant, classified in class 435, subclass 189.
- III. Claim 5-6, drawn to an antibody, which binds COX-1 variant polypeptide, classified in class 530, subclass 387.9.
- IV. Claim 8-18, drawn to a method for identifying a compound, which modulates a Cox-1 variants, classified in class 435, subclass 15.
- V. Claim 19-27, drawn to a method for identifying a compound that specifically binds to the polypeptide, classified in class 435, subclass 15.
- VI. Claims 28-41, drawn to a method for identifying a compound (polypeptide) or small molecule that differentially modulates a Cox-1 variants, classified in class 435, subclass 15.
- VII. Claims 42-55, drawn to a method for identifying compound that differentially binds to a Cox-1 variant, classified in class 435, subclass 15.

For each of inventions I-VII above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions I-VII and one of inventions of (A) – (E) and one of invention (1)-(6).

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- (A). protein of SEQ ID No: 2 or a nucleic acid encoding SEQ ID No: 2.
- (B). protein of SEQ ID No: 4 or a nucleic acid encoding SEQ ID No: 4.
- (C). protein of SEQ ID No: 6 or a nucleic acid encoding SEQ ID No: 6.
- (D). protein of SEQ ID No: 8 or a nucleic acid encoding SEQ ID No: 8.
- (E). protein of SEQ ID No: 10 or a nucleic acid encoding SEQ ID No: 10.

- (1). polypeptide comprising SEQ ID No: 14.
- (2). polypeptide comprising SEQ ID No: 16.
- (3). polypeptide comprising SEQ ID No: 18.
- (4). polypeptide comprising SEQ ID No: 20.
- (5). polypeptide comprising SEQ ID No: 22.
- (6). polypeptide comprising SEQ ID No: 24.

The inventions are distinct, each from the other because of the following reasons:

- 2. The DNA of Group I and the proteins of Group II and III, each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The DNA comprises a nucleic acid sequence and the proteins of Group II and III each comprise unrelated amino acid sequences. The DNA has other utility besides encoding the proteins such hybridization or probe, the proteins can be made by another method such as isolation from natural sources or chemical synthesis and the proteins have other utility besides acting as an antigen to induce the antibodies such as for diacylglycerol (DAG) production.
- 3. Inventions II and IV-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

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product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case protein can be used for inducing antibody.

4. Inventions polynucleotide Group I and antibody Group III are unrelated to the method of Group VIII as they are neither used nor made by the method of Group VII as they have different modes of operation, different functions.

5. Inventions polynucleotide Group I is unrelated to the methods of Groups IV-VII as polynucleotide of Group I is neither used nor made by the method of Group IV-VII as they have different modes of operation, different functions.

6. Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein can be used for the materially different process of inducing an antibody.

7. Inventions antibody Group III are unrelated to the methods of Group IV-VII as antibody is neither used nor made by the method of Group IV-VII as they have different modes of operation, different functions.

8. The methods of groups IV-VII are patentably distinct as they comprise unrelated steps, use different products and produce different effects.

9. The nucleic acid and proteins, and peptides of Group (A)-(E) and (1)-(6) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together

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and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent structurally different polypeptides and polynucleotide encoding them or peptides. Therefore, where structural identity is required, such as for hybridization or expression or antibody binding, the different sequences have different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37CFR 1.48b if one or more of the currently named inventors are no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the imitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal H. Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

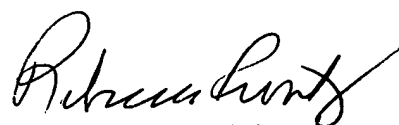
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

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